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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,819	01/07/2002	David R. Cox	1016	7783

7590

07/16/2003

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,819

Applicant(s)

COX ET AL.

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 08 April 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

SEQUENCE RULES

- 1.** This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

CLAIM OBJECTIONS

- 2.** Claim(s) 1-26 is/are is objected to for the following minor informality.

Claims 1, 6 and 10 are improper because they have periods within the body of the claim. Changing "a.", "b.", "c.", "d." to "a)", "b)", "c)", "d)" or to something similar thereto will overcome this objection.

35 USC § 112- 2ND PARAGRAPH

- 3.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

- 4.** Claim(s) 1-26 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because of the phrase in step d. which reads "based the results of step c)..." It appears the word "on" has been omitted from this phrase. Please clarify. .

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In addition, the phrase in Claim 1 which reads "based the results of step c),..." lacks proper antecedent basis in Claim 1 because step c of the method recited in Claim 1 is referred to as " c. " Please correct.

Claim 9 is unclear because the phrase which reads "used in step c),..." lacks proper antecedent basis in Claim 1 because step c of the method recited in Claim 1 is referred to as " c. " Please correct.

Claims 11 and 12 are unclear because the phrase "genetic DNA" in these claims lacks proper antecedent basis in Claim 1. Please correct.

35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

Claim Rejections under 35 USC § 102

6. **Claim(s) 1, 6, 10, 13-14, 17-18, 23** is/are rejected under 35 U.S.C. 102(a) as being anticipated by Patil et al. (23 NOV 01).

Patil et al. teach a method of performing genetic analysis which comprises all of the limitations recited in Claims 1, 6 and 10, 13-14, 17-18 and 23. Note that the critical limitations recited in Claims 17-18 are considered to be inherent to Patil et al.

35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

9. **Claim(s) 2, 7-8, 11-12 and 15-16** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Patil et al. (23 NOV 01).

Claim 2 is drawn to an embodiment of Claim 1 wherein the method further comprises using the blocks of variants in an association study whereby the blocks of variants are associated with a phenotypic trait.

Patil et al. teach all of the limitations of the method of performing genetic analysis recited in Claim 2 except these authors do not explicitly teach using the blocks of variants in an association study whereby the blocks of variants are associated with a phenotypic trait. However, at the bottom of Column 2 on page 1722, these authors do hint at using the blocks of variants in an association study whereby the blocks of variants are associated with a phenotypic trait. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Patil et al. wherein the blocks of variants are used in an association study whereby the blocks of variants are associated with a phenotypic trait.

Claim 7 is drawn to an embodiment of Claim 1 wherein said step of scanning genomic DNA comprises the step of sequencing said genomic DNA with a gel based sequencer. **Claim 8** is drawn to an embodiment of Claim 1 wherein said step of scanning genomic DNA comprises the step of sequencing said genomic DNA with a capillary based sequencer.

Patil et al. teach all of the limitations of the method of performing genetic analysis recited in Claims 7-8 except these authors do not explicitly teach sequencing said genomic DNA with a gel based sequencer or a capillary based sequencer. These authors do teach at the bottom of Column 3 on page 1719, sequencing genomic DNA using dideoxy sequencing but do not disclose the method of sequence analysis. However, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Patil et al. wherein any known method of sequence analysis is used. As both of the methods recited in Claim 7-8 were well known at the time of the invention, the use of either method, absent an unexpected result, would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention. The substitution of one well known method with known properties for a second well known method with known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 11 is drawn to an embodiment of Claim 1 wherein said step of scanning genetic (i.e. genomic) DNA to identify which of said variants occur in said additional individuals comprises the use of an Invader assay. **Claim 12** is drawn to an embodiment of Claim 1 wherein said step of scanning genetic (i.e. genomic) DNA to identify which of said variants occur in said additional individuals comprises the use of an Taqman assay.

Patil et al. teach all of the limitations of the method of performing genetic analysis recited in Claims 11-12 except these authors do not explicitly teach scanning genomic DNA via an Invader assay or a Taqman assay to identify which of said variants occur in said additional individuals. However, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Patil et al. wherein any known method of SNP analysis is used to identify the SNPs in the additional individuals. As both of the methods recited in Claims 11-12 were well known at the time of the invention, the use of either method, absent an unexpected result, would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention. The substitution of one well known method with known properties for a second well known method with

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known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 15 is drawn to an embodiment of Claim 1 wherein more than 1×10^8 bases are scanned for variants. **Claim 16** is drawn to an embodiment of Claim 1 wherein more than 1×10^9 bases are scanned for variants.

Patil et al. teach all of the limitations of the method of performing genetic analysis recited in Claims 15-16 except these authors do not explicitly teach scanning more than 1×10^8 bases and/or more than 1×10^9 bases for variants. However, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Patil et al. wherein more than 1×10^8 bases and/or more than 1×10^9 bases are scanned for variants. The motivation for making this modification comes from Patil et al. who teach "These findings suggest that any comprehensive description of the haplotype structure of the human genome, defined by common SNPs, will require empirical analysis of a dense set of SNPS in many independent copies of the human genome. As a first step toward achieving this goal, we have used high-density oligonucleotide arrays, in combination with somatic cell genetics, to identify a large fraction of all common human chromosome 21 SNPS and to directly observe the haplotype structure they define." This teaching would have motivated one of ordinary skill in the art at the time of the invention to modify the method disclosed by Patil et al. wherein the entire human genome (i.e. more than 1×10^9 bases) is scanned.

Additional Claim Rejections under 35 USC § 102

10. Claim(s) 1-3, 17-18 and 23 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Chew et al. [WO0104270 (18 JAN 01)].

Chew et al. teach a method of performing genetic analysis which comprises all of the limitations recited in Claim 1-3, 17-18 and 23. See at least page 8, beginning at about line 19 to line 31. Note that the IL4R α locus scanned comprises 28,690 basepairs including both introns and exons of the

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IL4R α gene. Also note that Chew et al. teach identifying blocks of variants wherein they produce IL4R α genome anthologies.

ADDITIONAL CLAIM REJECTIONS UNDER 35 USC § 103

11. Claim(s) 7-8 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Chew et al. [WO0104270 (18 JAN 01)] .

Claim 7 is drawn to an embodiment of Claim 1 wherein said step of scanning genomic DNA comprises the step of sequencing said genomic DNA with a gel based sequencer. Claim 8 is drawn to an embodiment of Claim 1 wherein said step of scanning genomic DNA comprises the step of sequencing said genomic DNA with a capillary based sequencer.

Chew et al. teach all of the limitations of the method of performing genetic analysis recited in Claims 7-8 except these authors do not explicitly teach sequencing said genomic DNA with a gel based sequencer or a capillary based sequencer. These authors do teach on page 57 under the section entitled "Examples" sequencing genomic DNA using well known (i.e. conventional methods) but do not disclose the exact method of sequence analysis used. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Chew et al. wherein any known method of sequence analysis is used. As both of the methods recited in Claim 7-8 were well known at the time of the invention, the use of either method, absent an unexpected result, would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention. The substitution of one well known method with known properties for a second well known method with known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.


CONCLUSION

12. Claim(s) 1-26 is/are rejected and/or objected to for the reason(s) set forth above.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN WHISENANT
PRIMARY EXAMINER**